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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,261	07/24/2003	Joel D. Oxman	56464US003	9585
32692	7590	04/19/2006	EXAMINER	
3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427			ROBERTS, LEZAH	
			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/626,261	<b>Applicant(s)</b> OXMAN ET AL.	
	<b>Examiner</b> Lezah W. Roberts	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on February 7, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) 11-14, 20, 36-39, 47 and 60-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15-19, 21-35, 40-46 and 48-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>A-D</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Response to Restriction/Election of Species Requirement***

Applicant's election with traverse of Group I and species elections of a mixture of Pluronic F127 and F68 as the thermally responsive viscosity modifier, PEGDMA, TEGDMA and IA:ITA:IEM as the polymerizable component, lidocaine hydrochloride as the additive, syringe as the method of application and oral surface as the surface in the reply filed on February 10, 2006 is acknowledged. The traversal is on the ground(s) that Groups I and II are so interrelated that a search of one group of claims will reveal art to the other. Moreover, the classification of Groups I and II claims in different classes and subclasses is not necessarily sufficient grounds to require restriction. This is not found persuasive because it cannot be determined if searches will reveal results until they are actually conducted.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-10, 15-19, 21-35, 40-46 and 48-59 will be examined on the merits.

Claims 11-14, 20, 36-39, 47 and 60-70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 10, 2006.

## ***Claims***

### **Claim Rejections - 35 USC § 102 - Anticipation**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1-7, 15-19, 21-30, 34-35, 40, 44-46, 48-49 and 53-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Joshi et al. (US 5,252,318).

Joshi et al. teach reversible gelation compositions and methods for delivering a pharmaceutical compound. The compositions comprise a temperature-sensitive reversibly gelling polymer and a pH-sensitive reversibly gelling polymer in an aqueous solution, which encompasses the instant claims. The temperature-sensitive polymers include polyoxyethylene and polyoxypropylene copolymers also known as Pluronics, which encompasses claims 2, 22 and 35. They are included at concentrations ranging from 0.1% to 40% by weight, which encompasses claim 22. The pH gelling polymers include acrylates, methacrylic acid and ethacrylic acid, which encompasses claims 3-6.

Art Unit: 1614

Cross-linking agents may be added to the compositions to create three dimensional polymer networks, which encompass claims 7, 34 and 40. They are incorporated into the compositions at concentrations ranging from 0.01 to 10%, which encompasses claim 21. Various pharmaceutical compounds may be incorporated into the compositions. Anesthetic agents that may be incorporated include lidocaine (col. 11, lines 60-65), which encompasses claims 18-19 and 45-46. The compositions may be applied as an oral, a nasal, rectal or subcutaneous. The preferred form of administration is a drop instillable, oral administration or injection (col. 12, lines 30-40), which encompasses claims 15-16 and 48-49. When the compositions are delivered to the body, the viscosity increases, which encompasses claims 23-25. Initial viscosities are preferably 100 to 30,000 cP and final viscosities range from 50,000 to 400,000 cP, which is more than 10 times the viscosity and encompasses claim 26, 53-54 and 56. The compositions are initially at 25°C, which encompasses claim 55. The reference anticipates the instant claims insofar as it teaches methods and compositions comprising thermally responsive viscosity modifier and a polymerizable component different than the modifier and water.

2) Claims 1-9, 15-19, 21-35, 40-46, 48-51 and 53-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Bromberg et al. (US 5,939,485).

Bloomberg et al. teach responsive polymer networks and methods of their use. The networks comprise a structural polymer made from monomers and a responsive polymer in an aqueous solution. The responsive polymers that may be used include

Art Unit: 1614

polyoxyalkylene polymers and copolymers, such as a block copolymer of polyoxyethylene and polyoxypropylene, which encompasses claims 2 and 35. The structural polymer is made from monomers, which include acrylic acid, methacrylic acid and ethacrylic acid. Adding an initiator such as free radical initiators, or UV or gamma radiation initiators polymerizes the monomers, which encompasses claims 7-9 and 40-42. The two components are incorporated into the compositions at concentrations ranging from 0.01 to 20 % (col. 15, lines 59-67), which encompasses claims 21-22. Exemplary drugs or therapeutics delivery systems which may be administered using the aqueous responsive polymer network compositions of the invention include mucosal therapies, such as esophageal, buccal oral, vaginal, and urological applications; topical therapies, such as wound care, skin care and teat dips; and intravenous/subcutaneous therapies, such as intramuscular, intrabone (e.g., joints), spinal and subcutaneous therapies, tissue supplementation, adhesion prevention and parenteral drug delivery, which encompasses claims 15-17, 30-31, 44 and 56. Drug that may be delivered by the invention include lidocaine, which encompasses claims 18-19 and 45-46. The compositions are reversible and viscosity increases at least by 5-fold, which encompasses claims 26 and 53-54. In the case of claims 27-28, if the temperature is lowered the gelling process will be reversed. The reference anticipates the instant claims insofar as it teaches methods and compositions comprising thermally responsive viscosity modifier and a polymerizable component different than the modifier and water.

3) Claims 1-10, 15-17, 21,23-25, 29-35, 40-44, 50-51, 55-56 and 58-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitra et al. (US 5,922,786).

Mitra et al. teach two part dental primers, which encompasses claim 51. The primers include a monomer or polymer or oligomer that may be polymerized using a free radical, a photoinitiator or redox system, which includes a oxidizing and reducing agent, so that the compositions may be polymerized during use (col. 8, lines 35-39). This encompasses claim 7-10, 34, and 40-43. The monomers include methacrylates and acrylic acids. The compositions comprise water, which makes them aqueous when the two parts are combined. The hydrophilic component of the system includes polymers and copolymers of polyalkylene oxides, which are thermally responsive viscosity modifiers. It can be concluded, the presence of the modifiers increases the viscosity of the compositions when applied to the surfaces of the mouth as recited in the instant claims. The reference anticipates the instant claims insofar as it teaches a two part compositions comprising thermally responsive viscosity modifier and a polymerizable component different than the modifier, water and an initiator.

4) Claims 1-10, 15-19, 29-35, 40-46, 48-52 and 55-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Bublewitz et al. (US 2002/0197214).

Bublewitz et al. teach one and two-part aqueous dental bleaching compositions. The supporting component comprising methacrylate monomers, which are polymerized by free radical polymerization and may contain initiators to speed up the polymerization process (paragraph 0059-0061). Initiators include redox initiators as well as

Art Unit: 1614

photoinitiators, which require a light source for polymerization. This encompasses claims 4-10 and 32-33. The second component may comprise a polyalkylene glycol including copolymers of polyethylene glycol and polypropylene glycol, which are thermal responsive polymers. This encompasses the instant claims. The two components are mixed together by static mixing using dual-chamber syringes (paragraph 0085), which encompasses claim 52. The compositions also comprise a whitening agent, which encompasses claims 18-19. The compositions are applied to the dental surface and hardened, which encompasses the instant claims. They may be applied with a paintbrush (paragraph 0027), encompassing claim 50. The reference anticipates the instant claims insofar as it teaches one and two part compositions comprising a thermally responsive viscosity modifier and a polymerizable component different than the modifier, water and initiators along with methods of preparing and using them.

### **Claim Rejections - 35 USC § 103 - Obviousness**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1614

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mitra et al. (US 5,922,786) in view of Murray (4,659,572).

The primary reference is disclosed above in the anticipation section subsection 3. The reference differs from the instant claim insofar as it does not teach mixing the disclosed compositions by static mixing.

Murray teaches compositions that have a delayed setting. They mix the components of the compositions by using static mixing. In-line static mixing devices are currently on the market. Devices of this type are ideally suited for dispensing delayed set liquid materials. One such device includes twin syringes, one of which is filled with the solution to be set, and the other is filled with the setting agent. Simultaneous extrusion of the two liquids through a disposable static mixing tube associated with the device is an effective and very convenient method of mixing the component liquids. This method also remedies degradation of the compositions when the two components are mixed together and stored. The mixing unit allows to mix the components before use (col. 15, lines 1-12). The reference differs from the instant claims insofar as it does not teach a method wherein the monomer unit of one component is polymerized.

It would have been obvious to one of ordinary skill in the art to have used the static mixing procedure in the method of the primary reference motivated by the desire to mix the two part compositions with efficiency, simultaneously and convenience as disclosed by the secondary reference.

Claims 1-10, 15-19, 21-35, 40-46 and 48-59 are rejected.

Claims 11-14, 20, 36-39, 47 and 60-70 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lezah Roberts  
Patent Examiner  
Art Unit 1614



Frederick Krass  
Primary Examiner  
Art Unit 1614

